IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004 4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	
LIABILITY LITIGATION	*	Case Nos. 4:13-cv-321 (Cole)

O R D E R

Defendant Mentor Worldwide LLC developed a suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. Plaintiff Linda Faye Cole was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Cole brought a product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Cole also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape. Mentor seeks summary judgment on all of Cole's claims. For the reasons set forth below, Mentor's summary judgment motion (ECF No. 40 in 4:13-cv-321) is granted in part and denied in part.

SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In determining whether a *genuine* dispute of

material fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A fact is *material* if it is relevant or necessary to the outcome of the suit. *Id.* at 248. A factual dispute is *genuine* if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id.*

FACTUAL BACKGROUND

Plaintiff Linda Faye Cole developed stress urinary incontinence and sought treatment from Dr. John Peacock. Dr. Peacock implanted Cole with ObTape on July 30, 2004. When Dr. Peacock implanted Cole with ObTape, Dr. Peacock had "significant clinical experience" with ObTape "that had been overwhelmingly positive." Peacock Dep. (*Cole*) 192:11-15, ECF No. 40-7 in 4:13-cv-321.

When deciding whether to use a medical device, Dr. Peacock wants as much clinically relevant information as possible; if relevant information is withheld, he cannot make a fully informed decision. Peacock Dep. (*Burch*) 153:24-154:8, ECF No. 42-10 in 4:13-cv-321.[1] When Dr. Peacock implanted Cole with

[1] Dr. Peacock implanted Barbara Burch, another plaintiff in this MDL, with ObTape on July 2, 2004. *Burch v. Mentor Corp.*, No. 2004 4:08-MD-2004-CDL, 2015 WL 5722799, at *1 (M.D. Ga. Sept. 29, 2015). Cole relies on the deposition testimony Dr. Peacock gave in *Burch* in addition to the testimony he gave in this case.

ObTape, he understood that the risks of certain adverse events with ObTape were fairly low. Peacock Dep. (*Cole*) 25:2-9, ECF No. 42-3. He reached that understanding based on his discussion with a Mentor representative and his review. *Id.* at 25:11-13. Dr. Peacock was aware of both "short and potentially long-term complications." *Id.* at 25:14-20. He also understood from the Mentor representative that ObTape "was a woven polypropylene mesh" that was less elastic than the material Dr. Peacock had been using. Peacock Dep. (*Burch*) 29:19-30:4. Dr. Peacock does not recall whether he reviewed the ObTape product insert data sheet. *Id.* at 63:20-23. Dr. Peacock testified that he would have wanted to know if ObTape could cause chronic inflammation, as well as the clinical relevance of ObTape's pore size. *Id.* at 114:2-11, 121:14-20, 123:14-124:7. Before he implanted ObTape in Cole, Dr. Peacock was not aware of "any differences in pore size other than [he] knew [ObTape] was smaller than the very coarse product that [he] was accustomed to using." Peacock Dep. (*Cole*) 32:11-24, ECF No. 42-3. Dr. Peacock knew that a larger pore size would promote more tissue ingrowth than a small pore size, but he did not know (and still does not know) "the pore size at which that cutoff is critical." *Id.* at 32:23-34:3. He also knew that if a pore did not go all the way through the ObTape, that could prevent macrophages from infiltrating the pore, but he did not know the clinical implications of some

blind pores and would not be surprised if some pores did not go all the way through ObTape. *Id.* at 34:14-35:12. According to Dr. Peacock, Mentor did not inform him that other doctors had reported a high erosion rate with ObTape. Peacock Dep. (*Burch*) 172:1-5. Though Dr. Peacock testified that he already had extensive experience with ObTape by July 2004 and had not seen such erosion rates, he also testified that he would want to know if other doctors were experiencing problems. *Id.* at 172:8-15. If he knew about the complications other doctors reported, that "might" impact his decision to continue using ObTape. *Id.* at 172:16-18.

After her ObTape implant surgery, Cole began to suffer chronic urinary tract infections and was placed on chronic antibiotic prophylaxis. Cook Decl. Ex. C, White Report 5-6, ECF No. 42-5 in 4:13-cv-321. She also began to experience recurrent urinary incontinence and pelvic pain. *Id.* at 6. Cole has never been diagnosed with an erosion or infection of her ObTape, and her entire ObTape is still in her body. Cole claims that ObTape caused recurrent incontinence, voiding problems, urinary tract infections, dyspareunia, vaginal and pelvic pain, and thigh and back pain. Two of Cole's treating physicians—Dr. Peacock and Dr. Bryant Williams—testified that there is nothing in Cole's medical records to suggest that she had complications associated

with her ObTape or that she had issues with poor tissue ingrowth of her ObTape.

Dr. Andrew Siegel, a board certified urologist and Cole's general causation expert, opined that the physical properties of ObTape can prevent tissue ingrowth and can cause chronic inflammation. Cook Decl. Ex. G, Siegel Report 4, ECF No. 42-9 in 4:13-cv-321. Dr. Siegel also opined that the physical properties of ObTape can cause pain and organ dysfunction. *Id.* Dr. Amanda White, a board certified urogynecologist and Cole's specific causation expert, also opined that ObTape's physical properties rendered it "prone to infection and extrusion." White Report 4.

Dr. White reviewed Cole's medical records and the depositions of Cole's treating physicians. She also relied on her extensive experience with urethral slings. Based on her review, Dr. White concluded that "ObTape is a substantial contributing cause of Ms. Cole's chronic bladder symptoms, including urgency and frequency, recurrent urinary tract infections, nocturia, pelvic pain, and dyspareunia, and need for subsequent procedures and treatments." White Report 7. She also opined that Cole's "recurrent urinary tract infections were likely caused by the material properties of the ObTape device." *Id.* Finally, she opined that "[t]he material properties of the ObTape transobturator sling, namely unwoven, thermally bonded

polypropylene microporous mesh are such that tissue in-growth with capillary penetration is prohibited. While bacteria are able to enter the graft, host defense mechanisms are unable to respond within the device secondary to the size of leukocytes and macrophages. The result is an encapsulated graft with acute and chronic inflammation." *Id.*

Cole asserts claims for negligence, strict liability design defect, strict liability failure to warn, breach of warranties, unjust enrichment, fraud, and negligent misrepresentation. Mentor seeks summary judgment on all of these claims. Cole does not challenge Mentor's summary judgment motion on her warranty and unjust enrichment claims, so the Court grants Mentor's summary judgment motion as to those claims.

DISCUSSION

Cole filed this action on July 9, 2013 in the United States District Court for the District of Minnesota. The case was transferred to this Court as part of a multidistrict litigation proceeding regarding ObTape. The parties agree for purposes of summary judgment that Minnesota law applies to Cole's claims. *See Cline v. Mentor Corp.*, No. 4:10-cv-5060, 2013 WL 286276, at *7 (M.D. Ga. Jan. 24, 2013) (concluding that Minnesota law applied to claims of non-Minnesota ObTape plaintiffs who brought their actions in Minnesota).

I. Design Defect Claims

Cole brings design defect claims under negligence and strict liability theories, asserting that ObTape had a design defect that caused her injuries. Mentor argues that Cole's claims fail for lack of causation. The Court disagrees.

First, Mentor contends that Cole did not point to any evidence to establish general causation: that ObTape is capable of causing the types of injuries Cole suffered. But Dr. Siegel testified that the physical properties of ObTape can prevent tissue ingrowth and can cause chronic inflammation. Siegel Report 4. He also opined that the physical properties of ObTape can cause pain and organ dysfunction. *Id.* And Dr. White opined that ObTape's physical properties rendered it "prone to infection and extrusion." White Report 4. Cole asserts that she suffered chronic infections and pain, along with other symptoms. Drs. Siegel and White opine that ObTape is capable of causing these types of injuries, so the Court is satisfied that the evidence from Drs. Siegel and White is sufficient to create a genuine fact dispute on general causation.

Second, Mentor asserts that Cole did not point to sufficient evidence to establish specific causation: that ObTape actually caused Cole's injuries. Again, Dr. White opined that based on her review of Cole's medical records, ObTape more likely than not was a substantial contributing cause of Cole's

injuries, including her recurrent urinary tract infections and pelvic pain. Dr. White further opined that the material properties of ObTape inhibited tissue ingrowth and permitted bacteria to enter the graft while preventing defense mechanisms like leukocytes and macrophages from responding—leading to Cole's injuries. Mentor contends that because Cole's treating physician believes that Cole did not experience poor tissue ingrowth or an encapsulated graft, the Court should ignore Dr. White's opinion. Based on the present record, the Court is not convinced that the difference in opinion between Dr. Peacock and Dr. White is a valid basis for excluding Dr. White's opinion at this time. The Court thus declines to ignore Dr. White's opinion and finds that it is sufficient to create a genuine fact dispute on specific causation. For these reasons, the Court denies Mentor's summary judgment motion as to Cole's design defect claims.

II. Failure To Warn, Fraud, and Misrepresentation Claims

Cole brings failure to warn claims under a strict liability theory, contending that Mentor did not adequately warn her physicians about the true risks of ObTape. Cole also brings fraud and negligent misrepresentation claims, asserting that Mentor made fraudulent and negligent misrepresentations to her physicians about the risks of ObTape. Mentor argues that Cole

has not presented enough evidence to create a genuine fact dispute on causation for these claims.

Under Minnesota law, a plaintiff claiming a failure to warn must show that "the lack of an adequate warning caused the plaintiff's injuries." *Tuttle v. Lorillard Tobacco Co.*, 377 F.3d 917, 924 (8th Cir. 2004) (applying Minnesota law). Thus, to establish causation on her failure to warn, fraud, and misrepresentation claims under Minnesota law, Cole must show that a different warning or an accurate disclosure of the risks of ObTape would have made a difference in her treatment. There must be some evidence that the product user (or, in cases like this one where the learned intermediary doctrine applies, the product user's doctor) "would have acted differently had the manufacturers provided adequate warnings." *Id.*

Cole pointed to evidence that Dr. Peacock relied on the representations of a Mentor representative when he began using ObTape. She also pointed to evidence that if Dr. Peacock had received information from Mentor regarding the true risks of ObTape—including the clinical relevance of the small pore size and the complications other doctors experienced with ObTape—that might have impacted his decision to use ObTape in July 2004. Based on this evidence, the Court is satisfied that there is a genuine fact dispute on causation for Cole's failure to warn,

fraud, and misrepresentation claims. Mentor is therefore not entitled to summary judgment on these claims.[2]

CONCLUSION

As discussed above, Mentor's summary judgment motion (ECF No. 40 in 4:13-cv-321) is granted as to Cole's warranty and unjust enrichment claims but denied as to Cole's design defect claims and her failure to warn, fraud, and misrepresentation claims based on pre-implant warnings and representations. Mentor's motion is granted as to any claims Cole asserted under a continuing duty to warn theory.

This action is ready for trial. Within seven days of the date of this Order, the parties shall notify the Court whether they agree to a *Lexecon* waiver.

IT IS SO ORDERED, this 28th day of November, 2016.

S/Clay D. Land
CLAY D. LAND
CHIEF U.S. DISTRICT COURT JUDGE
MIDDLE DISTRICT OF GEORGIA

[2] Cole focuses on her argument that a different pre-implant warning would have made a difference. She did not respond to Mentor's summary judgment motion on her continuing duty to warn claim or point to any evidence to support such a claim, such as evidence that her post-implant treatment would have been different had her doctors received different post-implant information from Mentor. Thus, if Cole did assert a continuing duty to warn claim, Mentor is entitled to summary judgment on it.